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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,000	12/02/2003	Randall K. Ribaudo	4239-67022	5472

36218 7590 05/01/2007
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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
05/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,000	RIBAUDO ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 37-65 is/are pending in the application.

4a) Of the above claim(s) 40-45,47,50,51 and 57-64 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 37-39,46,48,49,52-56 and 65 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of Group I and the species mutant B2m/B7.2 molecule paper filed 2/6/07 is acknowledged. The traversal is on the ground(s) that are elucidated said paper. This is not found persuasive because of the following reasons. Regarding applicants comments, Groups I-VI are distinct for the reasons elaborated in the Office Action mailed 10/11/06. Regarding applicants comments about undue burden, the M.P.E.P. § 803 states that: "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The restriction requirement enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed on the Examiner by the examination of additional Groups II-VI.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 40-45,47,50,51,57-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/6/07.

3. Claims 37-39,46,48,49,52-56,65 are under consideration.

4. Applicant is required to update the status of all US patent applications disclosed in the specification.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 46,48,49,52-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,682,741. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reason. Whilst the two sets of claims differ in scope, both sets of claims include claims which encompass fusion proteins containing human B2-microglobulin or human B-2 microglobulin S55V with a cell adhesion molecule (aka the molecules recited in claim 2). The various parameters recited in claims 52-56 of the instant application are recited in claims 8-15 of 6,682,741.

7. Claims 37-39,65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,682,741 in view of Chada et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reason. Whilst the two sets of claims differ in scope, both sets of claims include claims which encompass fusion proteins containing human B2-microglobulin or human B-2 microglobulin S55V with a cell adhesion molecule such as B7.2. Whilst claims 1-24 of US Patent No. 6,682,741 do not teach said molecule in a composition with an

antigen, Chada et al. disclose fusion proteins containing B2-microglobulin and a targeting ligand (see claim 4) and a composition of said fusion molecule and a gene delivery vehicle (see page 16, last sentence continued on next page) wherein the gene delivery vehicle includes viral systems which contain viral antigens (see page 12, last paragraph, continued on next page). Therefore the two sets of claims would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 37-39,65, 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) There is no support in the specification as originally filed for the invention of claim 48. Regarding applicants comments, the particular passages of the specification to which applicant refers do not disclose the scope of the limitation of claim 48 wherein said claim encompasses modified B2 microglobulin which binds Class I MHC with the same or less affinity than wild type B2 microglobulin.

b)There is no support in the specification as originally filed for the composition of claim 37. Whilst the original claims disclose a vaccine composition as per claim 37, the claimed composition is broader in scope than said disclosure (encompasses nonvaccine compositions and does not find support in the specification as originally filed). Regarding applicants comments, the first paragraph, page 16 refers to as B2 microglobulin preparation, not a preparation containing the components of claim 37. Furthermore, lines 7-10 of said passage refer to vaccination and the definition of "a clinically effective amount" which refers to the B2 microglobulin preparation of the

preceding sentence. Said passage refers to the definition of the term " a clinically effective" in the context of vaccination and is not a description of the limitation under consideration. The limitation under consider refers to nonvaccine compositions that are not disclosed in the specification. Example 1 discloses production of a B2 microglobulin fusion protein and does not disclose the limitation under consideration.

There is no written description in the specification as originally filed of the scope of the claimed invention (e.g. the claimed inventions constitute new matter).

10. Claims 37-39,46-49,52-56,65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

The instant claims recite use of hB2m S55V or B2 microglobulin. Regarding the term "hB2m S55V", according to the specification, page 7, lines 14-16, said term encompasses mutants of wild-type B2 microglobulin that contain the S55V mutation along with any additional amino acid sequence modifications. Thus, said claims encompass untold numbers of mutants of B2 microglobulin wherein said mutants would still possess the functional properties necessary that the claimed invention can be utilized for the purposes disclosed in the specification. There is no disclosure in the specification of such mutants other than the S55V mutant. The identity of such molecules other than S55V is not disclosed in the specification or art of record. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. The aforementioned definition would also apparently apply to

the term "B2 microglobulin" in view of the fact that said term is generic to the S55V mutation as per the original claims and there is no specific definition of said term in the specification. Regarding claims not restricted to human B2 microglobulin, the specification discloses that human, murine and bovine B2 microglobulin were known in the art. However, claims not restricted to human B2 microglobulin encompass B2 microglobulin form any of the thousands of mammalian species wherein said molecules are not known or disclosed in the prior art. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

11. Regarding the application of prior art, the claimed inventions are not entitled to priority to the parent applications to which priority is claimed because they lack written description for the reasons elucidated in this Office Action.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 37,46,52,53,55 are rejected under 35 U.S.C. 102(b) as being anticipated by Mottez et al.

Mottez et al. disclose a composition comprising the B2 microglobulin fusion protein of claim 37, part (b) and an antigen (Cw3) (see Figure 1, molecule on the right, Figure 2 and page 495, second column, continued on page 496 and page 494, second column, first paragraph). The Cw3 antigenic peptide functions as a "cell adhesion molecule" because it mediates binding to TCR on cells which express the appropriate TCR which binds said antigenic peptide (see page 497, first column). The molecules are joined at the amino terminus of the B2 microglobulin (see Figure 1). The molecule comprises a signal peptide joined to the first molecule (see Figure 2).

14. Claims 37,39,46,48,52,53 are rejected under 35 U.S.C. 102(b) as being anticipated by Chada et al. (WO 97/24446).

Chada et al. disclose a B2 microglobulin/EPO fusion protein (see Example 4) wherein EPO is the cytokine erythropoietin. The B2 microglobulin fusion protein can also contain other cytokines (see page 9, last paragraph). The B2 microglobulin and

EPO of the fusion protein are joined at the amino terminus of the B2 microglobulin (see page 28, last paragraph). Chada et al. disclose fusion proteins containing B2-microglobulin and a targeting ligand (see claim 4) and a composition of said fusion molecule and a gene delivery vehicle (see page 16, last sentence continued on next page) wherein the gene delivery vehicle includes viral systems which contain viral antigens (see page 12, last paragraph, continued on next page).

15. Claims 37-39,46,48,49,52-56,65 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribaudo et al. (WO 99/64597).
Ribaudo et al. disclose the claimed peptides (see abstract and claims 1-15). Ribaudo et al. disclose vaccine compositions containing the molecules recited in the claimed compositions (see claims 37-39). Ribaudo et al. disclose the peptide of claim 37(b) (see claim 8).

16. Claims 48,49 are objected to because of the following informalities. Claim 48, "class 1" should be "class I". Appropriate correction is required.

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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